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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/540,349

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Lars R. Damgaard

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EXAMINER

MARTIN, PAUL C

ART UNIT

PAPER NUMBER

1657

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DELIVERY MODE

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/540,349	<b>Applicant(s)</b> DAMGAARD ET AL.	
	<b>Examiner</b> PAUL C. MARTIN	<b>Art Unit</b> 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on 29 April 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 27,36-38,40,42,43,45,48,49,51-53,57,60-67 and 70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8, 10, 12, 13, 21, 30, 31, 68 and 71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Continuation of Disposition of Claims: Claims pending in the application are 1-3,8,10,12,13,21,27,30,31,36-38,40,42,43,45,48,49,51-53,57,60-68,70 and 71.

### **DETAILED ACTION**

Claims 1-3, 8, 10, 12, 13, 21, 27, 30, 31, 36-38, 40, 42, 43, 45, 48, 49, 51-53, 57, 60-68, 70 and 71. Claims 27, 36-38, 40, 42, 43, 45, 48, 49, 51-53, 57, 60, 61-67 and 70 are acknowledged as withdrawn. Claims 1-3, 8, 10, 12, 13, 21, 30, 31, 68 and 71 were examined on their merits.

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/29/2010 has been entered.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 8, 10, 13, 30, 31, 68 and 71 are newly rejected under 35 U.S.C. § 103(a) as being unpatentable over Katerkamp *et al.* (US 6,730,471 B1) as evidenced by Grenier Microplate Dimensions Guide (2007).

Katerkamp teaches a culture device for monitoring metabolic activity comprising a Microwell<sup>TM</sup> plate (Column 5, Lines 31-37), wherein each cylindrical well is defined by an oxygen permeable membrane (Column 8, Lines 19-23 and Fig. 5), a stagnant culture medium (inherently having a viscosity greater than or equal to water) such that an oxygen diffusion gradient is established (Column 8, Lines 30-35 and Fig. 6) and an oxygen detector comprising an oxygen sensitive membrane (Columns 10 and 11, Claims 1-2).

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Katerkamp *et al.* does not teach a device wherein the transverse dimension (interpreted by the Examiner as the diameter) of the wells of the Microwell™ is less than 1.5mm and the height of said compartment being larger than the transverse dimension or wherein the well has an adjustable bottom operable to change the dimensions and either increase or decrease the well volume.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Katerkamp *et al.* which taught a device for the monitoring of metabolic activity in any microwell plate to use a microwell plate with wells having transverse dimensions of less than 1.5 mm and the height of said compartment being larger than the transverse dimension because the changing of the dimensions of the well would have been a matter of artisan preference or a matter of utilizing the microwell plate which was available and does not patentably distinguish the claimed invention from the prior art. For example, the Grenier reference discloses that microwell plates are available in a wide range of dimensions including those having a well height being larger than the transverse dimension (deep well). The MPEP states:

*In Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

Further, the modification of the method of Katerkamp *et al.* to make the device further comprise an adjustable bottom is *prima facie* obvious. The MPEP states:

*In re Stevens*, 212 F.2d 197, 101 USPQ 284 (CCPA 1954) (Claims were directed to a handle for a fishing rod wherein the handle has a longitudinally adjustable finger hook, and the hand grip of the handle connects with the body portion by means of a universal joint. The court held that adjustability, where needed, is not a patentable advance, and because there was an art-recognized need for adjustment in a fishing rod, the substitution of a universal joint for the single pivot of the prior art would have been obvious.).

While the device of Katerkamp *et al.* is directed to the culture of cells, the limitation of an individual substantially spherical metabolizing particle (or cell) would not preclude the use of the device of Katerkamp for such a purpose. The MPEP states:

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established.

*In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)

While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997)

***Response to Arguments***

Applicant's arguments filed 04/29/2010 have been fully considered but they are not persuasive.

The Applicant argues that the wells of the microwell plate are relatively shallow insofar as their height dimension is significantly less than their transverse width and the oxygen gradient established is not linear as significant convection would be expected in a wide and shallow container of culture medium and that the reference does not discuss a "diffusion gradient" (Remarks, Pg. 12, Lines 13-22 and Pg. 13, Lines 1-2).

This is not found to be persuasive for the following reasons, the microwells depicted are not shown to scale therefore Applicant cannot definitively make any statement with regard to the dimensions shown therein. As discussed above, the Katerkamp *et al.* reference is not limited to any particular microwell and microwell plates are available in many and varying dimensions including the claimed dimensions and the selection thereof would have been a matter of artisan preference. The Examiner maintains that Katerkamp *et al.* meets the structural limitations of the instant invention and while some functional differences may arise in the manner of use, the reference nevertheless meets the claimed structural limitations.



That the graphical representations of the diffusion gradients (function) obtained when in actual use are not exactly the same does not diminish the structural similarities between the two devices. Applicant's allegation that Katerkamp *et al.* does not work through the principle of establishing an oxygen diffusion gradient is not found to be persuasive as the reference makes numerous references to just such a principle, see Column 2, Lines 20-40, Column 8, Lines 28-35 as well as Figures 2 and 6.

The Applicant argues that the addition of the new structural limitation to the claims specifying that the height dimension of the compartment (well) is larger than its transverse dimension is distinct from the compartment taught by Katerkamp *et al.* which allegedly utilizes a wide and shallow chamber for the containment of the culture medium and therefore teaches away from the present invention (Remarks, Pg. 13, Lines 10-20).

This is not found to be persuasive for the reasoning provided above, that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Katerkamp *et al.* which taught a device for the monitoring of metabolic activity in any microwell plate to use a microwell plate with wells having transverse dimensions of less than 1.5 mm and the height of said compartment being larger than the transverse dimension because the changing of the dimensions of the well would have been a matter of artisan preference or a matter of utilizing the microwell plate which was available and does not patentably distinguish the claimed invention from the prior art.

For example, the Grenier reference discloses that microwell plates are available in a wide range of dimensions including those having a well height being larger than the transverse dimension (deep well). The MPEP states:

*In Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

Claims 1-3, 8, 10, 12, 13, 21, 30, 31, 68 and 71 are newly rejected under 35 U.S.C. § 103(a) as being unpatentable over Katerkamp *et al.* (US 6,730,471 B1) as evidenced by Grenier Microplate Dimensions Guide (2007) and in view of Barker *et al.* (US 5,652,142).

The teachings of Katerkamp *et al.* were discussed above.

Katerkamp *et al.* does not teach a device comprising an insert for the adjustment of the transverse dimension of the compartment, or wherein a metabolite permeable layer is arranged in the bottom of the at least one compartment.

Barker *et al.* teaches a cell culture insert with a metabolite permeable layer at the bottom suitable for use with any a culture vessel with any number of wells (Column 3, Lines 15-47) and which permits a concentration gradient of nutrients to develop through the permeable membrane (abstract). It is inherent in the device of Barker *et al.* that the use thereof will result in a cell culturing compartment which has a smaller diameter than the culture well it is in.

It would have been obvious to one of ordinary skill in the art to combine the culture device of Katerkamp *et al.* for monitoring metabolic activity with the cell culture insert device of Barker *et al.* because doing so would allow one to create a concentration gradient of soluble nutrients/metabolites and gaseous metabolites in the culture well. One of ordinary skill in the art would have been motivated to make this combination so as to advantageously monitor metabolism of both gas and soluble nutrients. There would have been a reasonable expectation of success in making this combination because both devices are drawn to cell culturing and the creation of concentration gradients.

### ***Response to Arguments***

Applicant's arguments filed 04/29/2010 have been fully considered but they are not persuasive.

The Applicant argues that the Barker *et al.* reference shows a compartment in which the transverse dimension of the compartment is greater than its height, in contrast with the newly amended claims which specifically recite that the height dimension of the chamber is greater than its transverse dimension. Applicant further notes that the reference does not teach the establishment of any concentration gradient, much less a linear, diffusion gradient (Remarks, Pg. 14, Lines 3-15).

This is not found to be persuasive for the following reasons, as discussed above, Katerkamp *et al.* meets the structural limitations of the instant invention and while some functional differences may arise in the manner of use, the reference nevertheless meets the claimed structural limitations. The MPEP states:

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established.

*In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)

While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997)

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The Barker *et al.* patent was cited for its teaching of an insert used in a cell culturing system which may be positionable within a cell culturing system and its relation to the embodiments of the instant invention wherein an insert may be used for adjusting the dimensions of a culture well, not for any teaching regarding a diffusion gradient and as such remains pertinent Prior Art.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL C. MARTIN whose telephone number is (571)272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin  
Examiner  
Art Unit 1657

05/12/2010

/Rebecca E. Prouty/  
Primary Examiner,  
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